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(54) **Recyclable medication dispensing divice**

Wiederverwendbare Abgabevorrichtung für Medikamente

Appareil recyclable de distribution de médicaments

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Description

[0001] The present invention relates generally to medical dispensing devices and, more particularly, to a recyclable dispensing device that permits selectively measured dosages of a liquid to be dispensed.

[0002] Patients suffering from diseases such as diabetes must inject themselves several times each day with an insulin solution. Since the volume of insulin solution to be injected varies from injection to injection, it is necessary for such patients to be able to measure a precise volume of insulin. Diabetics have conventionally used a syringe for injection of insulin. However, it is difficult to control the operation of the syringe as well as the quantity of drug injected.

[0003] In order to permit a diabetic to measure and administer a more accurate and controlled dosage, injector pens have been developed which enable a particular dosage to be accurately and conveniently measured. Generally, these pens are secured onto a cartridge having a particular quantity of liquid medication sealed therein. The cartridge includes a plunger and a mechanism for advancing the plunger in the cartridge in such a manner to dispense the medication. Injector pens may be reusable or disposable. In reusable pens, a user can change a spent cartridge and reset the leadscrew of the pen back to its initial position. In a disposable pen, the cartridge is permanently captured in the pen which is disposed of after the contents of the cartridge have been exhausted.

[0004] One such disposable pen that has functioned very adequately is disclosed in U.S.. Patent No. 5,295,976. Specifically, a dispensing device is disclosed and includes an internally threaded collar and an externally threaded plunger rod. In order to set a dosage of medication to be delivered, the collar is rotated thereby causing displacement of the collar toward the proximal end of the injection device. Rotation of the collar causes the integral cap to become effectively displaced both rotationally and axially toward the proximal end of the pen. As this displacement occurs, the segment of the dose-indicating scale which is visible through a window varies showing a linear increase in the number to indicate an increase dosage of liquid to be dispensed. Once the desired dosage is selected, a force is applied to the end of the cap causing a linear displacement of the cap, integral plunger rod, and piston to dispense liquid from the container. The dispensing displacement of the plunger rod is halted by abutting contact between the cap and a stop element.

[0005] In U.S. Patent No. 5,308,340, another recyclable injection device is disclosed. In particular, a plunger rod is received within the housing for exerting a force on a piston closing a second end of the container. The plunger rod has a noncylindrical cross section with a first surface including threads and a second surface which can, optionally, include a series of ratchet teeth. A collar is received within the housing adjacent the second end of the container for permanently retaining the container of liquid within the housing. The plunger rod passes through the noncylindrical opening in the collar and is prevented from rotating with respect to the housing by the collar. A hollow cap envelopes the plunger rod opposite the container of liquid. The skirt of the hollow cap extends inside the housing. The cap includes a threaded interior surface which movably engages the plunger rod for calibrated adjustment relative thereto. A stop is provided within the housing, and a distal facing surface is provided on the hollow cap for contacting the stop upon linear movement of the cap and plunger rod as a unit toward the container to dispense liquid therefrom. In operation, the cap is rotated in a counterclockwise direction causing the threads of the cap to travel along the threaded portion of the rod. This rotation does not cause displacement of the plunger rod with respect to the housing, but backs the distal end of the proximal cap portion away from a stop shoulder on the inside of the housing. When the cap has been positioned to the desired dosage, pressure is applied to the end of the cap for causing it to move linearly toward the distal end of the housing until a shoulder defined by a radially exposed portion of the distal end contacts a stop.

[0006] European patent application EP-A-0268191, which is used as a basis for the preamble of claim 1, and PCT application WO-A-9218179 disclose further apparatuses for delivery of an injectable product.

[0007] According to the present invention there is provided an apparatus (20) for the delivery of an injectable product, comprising:

a housing (22);

a container (40) mounted within said housing (22) and including a piston (210), an exit and an injectable product between said piston (210) and said exit, wherein movement of said piston (210) toward the exit defines an axis of ejection of the injectable product from the container (40); and

a drive stem (38) disposed in said housing (22) and drivingly coupled to said piston (210);

a drive assembly (34) mounted to said housing (22) and manually axially advanceable in said housing (22) between a dose-setting position and an injection position for manually moving said drive stem (38) to drive said piston (210) within said container (40), said drive assembly (34) being locked from movement with respect to said housing (22) along the axis of ejection while in said dose setting position, and a disengaging device (32) secured to at least one of said drive assembly (34) and said housing (22) and manually actuable to unlock said drive assembly (34) from said housing (22) to enable said drive assembly (34) to be axially advanceable with respect to said housing (22) to move said drive assembly (34) from said dose setting position to said injection position,

said drive assembly (34) is a generally cylindrical dial (34) that is telescopingly disposed within said housing (22), said dial (34) having a flexible finger (110,112) formed therein that engages an internal groove (158) in said housing (22) while said drive assembly (34) is in said dose-setting position to form an interference fit therebetween, thereby preventing axial movement of said drive assembly (34) with respect to said housing (22); characterised in that said disengaging device (32) is a generally cylindrical button (32) that is telescopingly disposed within said dial (34), said button (32) including an enlarged diameter portion (52), which when advanced, disengages said flexible finger (110, 112) of said dial (34) to allow said finger (110, 112) to move out of engagement with said groove (158) in said housing (22) to enable said drive assembly to be axially advanced with respect to the housing (22).

[0008] In particular, the present invention provides a medication injection device comprising a housing, a dose setting mechanism within the housing, and a delivery mechanism within the housing for advancing a leadscrew. A liquid medication product is housed in a variable volume cartridge within the housing of the device. Upon actuation of the delivery mechanism, the leadscrew is advanced against a movable piston in the cartridge to advance the piston thereby causing a preset quantity of medication to be delivered out of the needle of the device.

[0009] The device is made entirely out of a recyclable plastic material, except for the glass container, steel needle and label. The dose setting mechanism comprises a dial assembly including a clutching device for engaging and disengaging a generally cylindrical internally threaded nut, which is threaded onto an externally threaded leadscrew. A dose is set by rotating the nut with respect to the leadscrew. The nut is rotated by rotating the dial. However, the nut must be engaged with the dial so that rotating the dial also rotates the nut. The clutching device comprises a series of splines on the inner cylindrical surface of the dial which axially engage corresponding splines on the outer surface of the nut. The splines are engaged with one another by retracting the dial with respect to the nut after the dial has been rotated to its zero dose position.

[0010] The dial assembly includes a mechanism that prevents the user from retracting the dial prior to rotating the dial to its zero dose position. This mechanism comprises a finger formed in the housing that rides within a groove formed at the distal end of the dial assembly as the dial assembly is rotated. The dial cannot be pulled out in any radial position other than the zero dose radial position due to the interference formed between the finger and the walls of the groove. In the zero dose position, the housing finger rides up within a spline that extends axially uninterrupted to enable the dial to be proximally retracted with respect to the housing only when the dial is in its zero dose radial position.

[0011] The device includes a mechanism that limits the maximum dosage that can be set. This mechanism comprises a helical groove formed in the housing and a pair of flexible fingers formed in the dial assembly. Upon rotating the dial to set a dose, the dial is retracted with respect to the housing because the dial fingers ride up the internal housing groove. Once the dial fingers reach the proximal end of the housing groove, further rotation of the dial is prohibited, thereby indicating to the user that the maximum dosage has been dialed.

[0012] According to the invention, the device further includes a mechanism for automatically locking out the dial from an inadvertent injection after the dial has been retracted to set a dosage. This lockout mechanism comprises the above-mentioned fingers in the dial assembly that fall into the helical groove in the housing upon retracting the dial with respect to the housing. The interference fit formed by the fingers in the groove prevents forward movement of the dial in the event of inadvertent pressure being applied to the end of the dial. The lockout mechanism is released by a button assembly that is disposed within the proximal end of the dial assembly. The button assembly is sized and configured so that it must be depressed upon initiating an injection. Upon depressing the button assembly, it bottoms out against the dial, whereupon the dial moves forwardly so that the flexible fingers move past the groove in the housing.

[0013] One of the two flexible fingers of the dial assembly has an extension which, when the button is pressed, is pushed radially out. This finger falls within a separate groove in the housing as the "end-of-dose" stop surface of the dial engages the corresponding stop surface on the housing, thereby producing an audible "click" indicating that the entire dosage has been injected. The housing further includes radially inwardly extending tangs at the proximal end thereof which engage ratchet teeth in the leadscrew to prevent the leadscrew from backing up in the proximal direction. These tangs are in constant engagement with the leadscrew, thereby preventing the leadscrew from rotating upon rotation of the nut.

[0014] An advantage of the medication dispensing device of the present invention is that the dosing function is locked out until the dial has been rotated to its zero dose position, thereby ensuring an accurate dosage.

[0015] Another advantage of the present invention is that the device is an inexpensive recyclable pen that is designed to allow a user to dose in single unit increments, which are each displayed in a single unit display.

[0016] Another advantage of the present invention is that the end-of-dose click arrangement is adjacent the end-of-dose stop to provide increased accuracy of an end of dose.

[0017] Another advantage of the present invention is that the device includes a dosage lockout mechanism that prevents an inadvertent delivery of a dosage of medication.

[0018] Yet another advantage of the present invention

is that the device is made of inexpensive materials and is nearly 100% recyclable after the contents of the cartridge have been depleted.

Fig. 1 is a perspective view of one embodiment of a medication dispensing device in accordance with the present invention;
Fig. 2 is an exploded view of the device of Fig. 1;
Fig. 3 is an enlarged longitudinal sectional view of a portion of the medication dispensing device of Fig. 1, particularly showing the button assembly disposed within dial assembly;
Fig. 4 is an enlarged perspective view, in partial section, of the medication dispensing device of Fig. 1, particularly showing the button assembly disposed in the dial assembly;
Fig. 5 is an enlarged cross sectional view of the medication dispensing device of Fig. 1, particularly showing the insufficient remaining dose stop on the nut approaching the corresponding stop on the leadscrew;
Fig. 6 is a view of Fig. 5, except that the insufficient remaining dose stop on the nut is in engagement with the stop on the leadscrew;
Fig. 7 is a perspective view, in partial section, of a housing part in engagement with the dial assembly, particularly showing the unit click finger in the zero position;
Fig. 8 is a view of Fig. 7, except that the unit click finger is behind the end-of-dose flange;
Fig. 9 is a view of Fig. 7, except that the unit click finger is shown in the dial splines during dosing;
Fig. 10 is an enlarged sectional view of a portion of the medication dispensing device of Fig. 1, particularly showing the relationship among the button assembly, dial assembly, and housing while the device is at the end of dose position;
Fig. 11 is a longitudinal sectional view of the medication dispensing device of Fig. 1, particularly showing the dial assembly after it has been rotated to the zero position;
Fig. 12 is a view of Fig. 11 except that the dial assembly has been retracted so that the splines of the nut are engaged by the splines of the dial assembly;
Fig. 13 is a view of Fig. 12, except that a desired dosage has been dialed up;
Fig. 14 is a view similar to Fig. 10, showing the dial assembly rotated 180°, and further showing the button initially depressed before dial movement takes place;
Fig. 15 is a view of Fig. 14, showing the dial having moved forward a small distance;
Fig. 16 is a view of Fig. 14, showing the dial having moved forward half of a thread pitch; and
Fig. 17 is a view of Fig. 13, except that the pen is shown in its end-of-dose position.

[0019] For purposes of this application, the term "proximal" shall designate a relative axial position toward the knob end of the delivery mechanism, and the term "distal" shall designate a relative axial position toward the delivery needle end of the delivery mechanism.

[0020] Referring to Figs. 1 and 2, there is shown an injection medication device 20 having the general appearance of a pen or mechanical pencil. The device comprises a mechanism housing 22 having a first part 24 and a second part 26 (Fig. 2). Housing parts 24 and 26 are secured together in a suitable fashion, e.g. chemical bonding with a suitable adhesive or a solvent. A cap 28 is snapped onto the distal end of mechanism housing 22. Cap 28 includes a clip 30 which cooperates with the side wall of cap 28 to provide a convenient means for holding the pen device 20 in a shirt pocket. Referring to Fig. 2, the major components of medication device 20 include a button assembly 32, a dial assembly 34, a nut 36, and a leadscrew 38. A cartridge 40 is inserted into a distal body 42 to which is attached a needle assembly 44 and needle cover 46. All of the components of medication device 20, except cartridge 40 and needle 44 may be made of a plastic material that is suitable for recycling. Suitable plastics are high flow polycarbonates resins which can be processed by conventional injection molding and extrusion. In one embodiment, the housing parts 24, 26 and distal body 42 are made from an optically clear polycarbonate material, and the remaining plastic components are made from ABS resins. These plastics are recyclable, thereby making disposal of the device environmentally desirable.

[0021] Referring to Fig. 4, button assembly 32 comprises a hollow cylindrical portion 48 having a proximal end 50. Cylindrical portion 48 includes a distal end 52 in the form of an annular bead and further includes an enlarged diameter ring 54 comprising a tapered surface 56 and an enlarged diameter flat surface 58. The inner section of surfaces 56 and 58 forms an enlarged diameter shoulder surface 60. The proximal end 50 of button assembly 32 comprises two flexible fingers 62, 64, each extending from a base surface 66. As shown in Fig. 4, each finger 62, 64 is L-shaped and includes a first leg which extends from base surface 66 and is parallel with the axis of medical device 20, and a second leg extending radially about 90° from the first leg. Proximal end 50 of button assembly 32 further includes a finger-engageable end 68 having a recessed surface 70. End 68 is integrally connected to hollow cylindrical portion 48 by connection portions 72 (Fig. 3). Proximal end 68 includes a surface 74 (Fig. 3) that is formed from reduced length portion 76.

[0022] Referring to Figs. 3 and 10, dial assembly 34 is shown in detail. Dial assembly 34 is generally cylindrical in shape and is hollow throughout its axial length. The diameter of dial assembly 34 is at a maximum at its proximal end and is at a minimum at its distal end. Referring to Fig. 3, dial assembly 34 comprises a proximal portion 78, an intermediate portion 80, and a distal portion 82. Proximal portion 78 comprises an enlarged di-

ameter portion 84, a tapered portion 86, and an end-of-dose ring 91 extending about the circumference of proximal portion 78 as shown in Fig. 3. Ring 91 includes a bottom surface 89 (Fig. 13) that constitutes a stop surface when engaged with the rear of the housing. Ring 91 also includes an enlarged "zero-dose" protrusion 88. A generally U-shaped groove 90 (Figs. 2, 3) is formed in proximal portion 78 to form a flexible section 92. The proximal inner surface of flexible section 92 includes a finger 94 having a tapered surface 96 adapted for engagement with tapered surface 56 of button assembly 32 and a complimentary tapered surface 98.

[0023] Proximal portion 78 of dial assembly 34 further includes a first U-shaped groove 100 (Fig. 2) and a second U-shaped groove (not shown) which form flexible legs 102, 104. Referring to Fig. 10, each leg 102, 104, includes an inwardly extending finger 106, 108, and an outwardly extending finger 110, 112, distal to the inwardly extending finger. Inwardly extending finger 106 includes proximal tapered surface 114, flat 116, and distal tapered surface 118. Likewise, finger 108 includes proximal tapered surface 120, flat 122, and distal tapered surface 124. Outwardly extending finger 110 comprises a proximal tapered surface 126, a flat 128, shoulder 130, enlarged diameter surface 132, and distal tapered surface 134. Inwardly extending finger 112 includes a proximal tapered surface 136, a shoulder 138, an enlarged diameter surface 140, and a distal tapered surface 142.

[0024] Referring to Fig. 3, a series of axial splines 142 are arranged circumferentially about the inner surface of dial assembly 34 at the area where proximal portion 78 meets intermediate portion 80. The circumferential array of splines 142 is interrupted by legs 102 and 104. In one embodiment, there are ten splines 142 positioned about the inner circumference of dial assembly 34. Referring to Figs. 3 and 10, there is shown a plurality of splines 144 extending circumferentially about the proximal interior surface of intermediate portion 80 of dial assembly 34. Unlike splines 142, splines 144 extend 360° about the inner circumference of intermediate portion 80. In one embodiment, eighteen splines 144 are positioned such that each spline is 20 circumferential degrees apart from an adjacent spline.

[0025] As best shown in Figs. 7-9, distal portion 82 of dial assembly 34 comprises a proximal flange 146, a reduced diameter portion 148, and a distal end comprising a series of elongated splines 150 extending externally about the circumference of distal portion 82. Splines 150 are in alignment with splines 144. Therefore, in one embodiment, there are eighteen splines 150, each corresponding to a respective spline 144. As shown in Figs. 8 and 9, two of the splines 150 extend axially into reduced diameter portion 148. These extensions are indicated as splines 152.

[0026] Referring to Fig. 10, housing parts 24 and 26 form a proximal groove 154 having a tapered surface 156. Housing parts 24 and 26 further form a helical spiral groove 158 and a tapered circumferential surface 160 as shown in Fig. 10. Housing part 24 further includes a semicircular ridge 164 near the distal end thereof. Two grooves are formed at the distal portion of housing part 24 to define a flexible finger 166. Housing part 26 includes grooves formed therein to define a flexible leg 168 having an inwardly extending finger 170 at the end thereof. Finger 170 includes a proximal tapered surface 172 which terminates in a flat 174 and a vertical edge 176. Housing parts 24 and 26 include transverse ledges 178, 180, respectively, to reduce the diameter through the proximal end of the housing. Ledges 178 and 180 include flexible tangs 182, 184, respectively.

[0027] As best shown in Figs. 11-13 and 17, medical delivery device 20 further includes nut 36 and leadscrew 38. Nut 36 is generally cylindrical in shape and includes a pair of axially extending grooves 186 (Fig. 2) to form resilient proximal legs 188. Each leg 188 includes a proximal raised portion 190 and two small axially extending splines 192. The distal end of nut 36 comprises an enlarged gear-like member 194 having a plurality of teeth 196 thereon. The interior surface of the distal end of nut 36 includes a helical thread 198. Thread 198 extends about 350° about the inner surface of nut 36. A groove 200 is formed at the distal end of leadscrew 38 to form legs 226, 228 (Fig. 2). Ratchet teeth 204 are located on two opposing sides of leadscrew 38 and axially extend along the length of leadscrew 38 from groove 200 to the distal end, which constitutes plunger engagement portion 206. Helical threads 208 extend along the axial length of leadscrew 36 legs 226, 228. Leadscrew 38 fits within the cylindrical opening of nut 36.

[0028] As shown in Figs. 11-14, plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40. Cartridge 40 is housed within cartridge retainer 42, which is permanently secured to housing parts 24 and 26. Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover. Needle assembly 44 comprises an internally threaded base 220 and a delivery needle 222. Internally threaded base 220 is threaded onto externally threaded distal portion 224 of body 42. Needle cap 46 fits over needle 222 to prevent an inadvertent insertion of needle 222 into the patient. Cap 28 snaps onto cartridge body 42 to complete the pen-like mechanism.

[0029] In order to set a dose for injection, it is first necessary to manually zero the dial from the initial radial position of the dial resulting from the previous injection. The initial radial position of dial assembly 34 with respect to housing part 26 is shown in Fig. 8. Specifically, finger 170 of housing part 26 is located in groove 148 of dial assembly 34. Groove 148 can be rotated by rotating dial assembly 34 with respect to the housing. Dial assembly 34 cannot be axially retracted due to the interference between vertical edge 176 of housing finger 170 and ledge 149 of dial assembly 34. Likewise, dial assembly 34 cannot be forced axially forwardly due to the

interference between surface 89 on ring 91 and end surfaces 33, 35 (Fig. 4) of housing parts 24, 26, respectively. If the user mistakenly believes that it is necessary to depress button assembly 32 to pull out the dial, finger 94 falls into groove 154 (Fig. 10), thereby creating an interference that prevents the dial from being pulled out. Upon continued rotation of dial assembly 34 with respect to housing 26, splines 152 are moved into engagement with finger 170, as shown in Fig. 7. This is the zero dose radial position of dial assembly 34. This zero dose position is communicated to a user in four ways. The user hears a click as splines 152 engage finger 170. The movement of finger 170 over the first spline 152 into the V-shaped recess 155 between splines 152 causes a vibration in device 20 that can be felt by the user. In addition, protrusion 88 on dial assembly 34 is in axial alignment with protrusion 153 of housing part 24, thereby providing a visual indication that the zero dose position has been reached. This is further visually communicated by the presence of a symbol in lens 25.

[0030] A series of numerals (not shown) are printed on the surface of intermediate portion 80 of dial assembly 34. These numerals are helically spaced about the circumference of portion 80 and may number from 1 to 60, in single increments, to indicate a desired dosage. The lens 25 in housing part 24 is aligned with the numbers so that the appropriate number appears in the lens upon dialing up the dosage. A raised rectangular portion lens 162 (Fig. 10) of lens 25 is located at the base of lens 25 to enhance the numerals thus making them easier to read.

[0031] In its zero dose position, dial assembly 34 may be axially retracted a predetermined distance, e.g. 3 to 5 mm, as illustrated in Fig. 12. As dial assembly 34 is retracted, ledge 149 is moved past housing finger 170 resulting in housing finger 170 being in engagement with splines 150. In addition, splines 144 of dial assembly 34 are moved into engagement with splines 192 of nut 36, as shown in Fig. 12. When engaged, rotation of dial assembly 34 causes corresponding rotation of nut 36. Rotation of leadscrew 38 is prevented by a key-keyway type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38. As shown in Fig. 6, tangs 182, 184 form a key, and leadscrew 38 forms a keyway which comes into contact with the sides of the key.

[0032] Upon rotation of dial assembly 34, fingers 110, 112 move within housing groove 158 in the proximal direction to retract dial 34, thereby increasing the axial distance between stop surface 89 of ring 91 and stop surfaces 33, 35 of housing parts 24, 26. Rotation of dial assembly 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance. As shown in Fig. 9, rotation of dial assembly 34 causes splines 150 to move past housing finger 170. The rotation of each spline 150 past finger 170 constitutes a single unit of dosage. As each spline 150 moves past finger 170, it causes a "click" to occur, thereby providing an audible indication of each unit of dosage dialed up. In addition, a single numeral appears in lens 25 after each unit rotation indicating the current dose selected. Once a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction.

[0033] In one embodiment, dial assembly 34 includes eighteen splines 150 spaced 20° apart from one another. It is desired to limit the amount of dosage that can be dialed to prevent the entire contents of cartridge 40 to be delivered at once. For example, it may be desirable to limit a measured dosage to a maximum of 60 units. If the dial assembly includes eighteen splines, this would mean that a user could rotate the dial assembly for nearly 3 1/2 rotations. As shown in Figs. 12 and 13, as a dosage is being set, outwardly extending fingers 110 and 112 of dial assembly 34 ride in helical groove 158 of housing parts 24 and 26. Once a predetermined maximum dosage has been dialed up, e.g. 60 units, fingers 110 and 112 have reached the proximal end of the helical groove 158. Dial assembly 34 cannot be additionally rotated to further increase this maximum dosage due to an interference ledge at the end of helical groove 158. Button assembly 32 prevents the dial assembly 34 from being inadvertently pushed forwardly during the dosing process due to the interference between fingers 110, 112 of dial assembly 34, button surface 52, and helical spiral groove 158 in housing parts 24, 26, as shown in Fig. 4. Fingers 110, 112 must be moved out of groove 158 before the dial may be moved axially forwardly. Fingers 110, 112 can be moved out of engagement with groove 158 only after fully depressing button assembly 32, thereby moving distal button surface 52 out of engagement with fingers 110, 112.

[0034] Once a desired dosage has been set, cap 28 is removed and needle cover 46 is removed to expose needle 222. The needle is inserted into the patient, and recessed surface 70 of button assembly 32 is pushed. Figs. 14-16 illustrate the initial stages of the injection process. Referring to Fig. 14, as button surface 70 is pushed, button assembly 32 moves forwardly independently of dial 34 until button distal surface 52 bottoms out against internal dial shoulder 141. Thereafter, button 32 and dial 34 are moved together. Referring to Fig. 15, as dial 34 begins to move forwardly, tapered finger surfaces 134, 142 are forced out of their respective threads 158. This causes fingers 110, 112 to flex radially inwardly. As button 32 is further pressed, fingers 110, 112 move out of respective threads 158, as shown in Fig. 16. As button 32 continues to be pressed, fingers 110, 112 move into and out of the remaining threads 158 in a like manner until dial 34 reaches its end of dose position shown in Figs. 10 and 17. The movement of edge 95 (Fig. 4) of dial finger 94 past housing edge 157 (Fig. 4) and into groove 154 (Fig. 10) creates an audible "click" sound, thereby providing an audible confirmation that the entire dosage has been injected. Finger 94 is in

close proximity to stop surfaces 89 and 33, 35.

[0035] As dial 34 is initially moved forwardly, splines 144 move out of engagement with splines 192 of nut 36 to decouple dial 34 from nut 36 prior to any axial movement of nut 36. Dial 34 moves axially with respect to nut 36 until the distal end 193 (Fig. 13) of dial 34 engages nut flange 194 and moves nut 36 and leadscrew 38 forwardly to deliver the set dosage of fluid.

[0036] Referring to Figs. 10 and 17, forward movement of dial assembly 34 and nut 36 is limited by the engagement of surface 89 of ring 91 with proximal end surfaces 33, 35 of housing parts 24, 26, respectively, as shown in Fig. 14. Referring to Fig. 14, there is a small clearance, e.g. 0.4 millimeters, between nut gear or flange 194 and internal ledges 178, 180 of housing parts 24, 26, respectively. In another embodiment, the end-of-dose stop may be designed to occur between nut flange 194 and ledges 178, 180.

[0037] Movement of leadscrew 38 is prevented in the proximal direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204. This assures that head 206 of leadscrew 38 remains at all times in constant engagement with piston 210.

[0038] Once a dosage has been completed, the user releases his finger from recessed button surface 70. Upon releasing pressure from surface 70, the flexible fingers or springs 62, 64 return from their stressed conditions back to their relaxed conditions, thereby automatically retracting the button assembly 32 back to the automatic lockout position shown in Fig. 11 to prevent the dial assembly 34 from being inadvertently advanced when it is again moved to its retracted position.

[0039] Medication device 20 further includes a mechanism to indicate to the user that there is an insufficient dosage of medication 212 remaining in cartridge 40. Referring to Figs. 5 and 6, leadscrew 38 comprises two legs 226 and 228. Leg 226 may be of a greater thickness than leg 228. Leg 226 includes an axially extending raised ledge 230 at the end of external thread 208. Leg 228 contains the end 232 of external thread 208. The internal helical thread 198 of nut 36 defines a stop surface 234 due to the fact that thread 198 extends less than 360° in circumference. As shown in Fig. 17, nut 36 moves toward legs 226, 228. of leadscrew 38 as leadscrew 38 moves within cartridge 40. Once nut 36 has axially moved entirely along thread 208 of leadscrew 38, stop 234 approaches axial ledge 230, as shown in Fig. 5. Additional rotation of nut 36 results in stop 234 engaging ledge 230, as shown in Fig. 6. This prevents the user from dialing up a higher dosage. Nut 36 may be rotated back in the opposite direction to reduce the dosage if desired. This rotational stop mechanism provides a very accurate indication to the user of the dosage remaining in the cartridge.

Claims

1. An apparatus (20) for the delivery of an injectable product, comprising:

   a housing (22);
   a container (40) mounted within said housing (22) and including a piston (210), an exit and an injectable product between said piston (210) and said exit, wherein movement of said piston (210) toward the exit defines an axis of ejection of the injectable product from the container (40); and
   a drive stem (38) disposed in said housing (22) and drivingly coupled to said piston (210);
   a drive assembly (34) mounted to said housing (22) and manually axially advanceable in said housing (22) between a dose-setting position and an injection position for manually moving said drive stem (38) to drive said piston (210) within said container (40), said drive assembly (34) being locked from movement with respect to said housing (22) along the axis of ejection while in said dose setting position, and a disengaging device (32) secured to at least one of said drive assembly (34) and said housing (22) and manually actuable to unlock said drive assembly (34) from said housing (22) to enable said drive assembly (34) to be axially advanceable with respect to said housing (22) to move said drive assembly (34) from said dose setting position to said injection position, said drive assembly (34) being a generally cylindrical dial (34) that is telescopingly disposed within said housing (22), said dial (34) having a flexible finger (110,112) formed therein that engages an internal groove (158) in said housing (22) while said drive assembly (34) is in said dose-setting position to form an interference fit therebetween, thereby preventing axial movement of said drive assembly (34) with respect to said housing (22); **characterised in that in that** said disengaging device (32) is a generally cylindrical button (32) that is telescopingly disposed within said dial (34), said button (32) including an enlarged diameter portion (52), which when advanced, disengages said flexible finger (110, 112) of said dial (34) to allow said finger (110, 112) to move out of engagement with said groove (158) in said housing (22) to enable said drive assembly to be axially advanced with respect to the housing (22).

Patentansprüche

1. Gerät (20) zur Abgabe eines injizierbaren Erzeugnisses, enthaltend:

ein Gehäuse (22);

einen in dem Gehäuse (22) angebrachten Behälter (40) mit einem Kolben (210), einem Ausgang und einem injizierbaren Erzeugnis zwischen dem Kolben (210) und dem Ausgang, wobei eine Bewegung des Kolbens (210) in Richtung auf den Ausgang eine Ausspritzachse des aus dem Behälter (40) injizierbaren Erzeugnisses bestimmt; und

einen Antriebsstempel (38), der in dem Gehäuse (22) angeordnet ist und antriebsmäßig mit dem Kolben (210) gekoppelt ist;

eine Antriebsanordnung (34), die in dem Gehäuse (22) angebracht ist und manuell in axialer Richtung innerhalb des Gehäuses (22) zwischen einer Dosiseinstellposition und einer Injizierposition manuell verschiebbar ist, um den Antriebsstempel (38) manuell zu bewegen, um den Kolben (210) innerhalb des Behälters (40) anzutreiben, wobei die Antriebsanordnung (34) in der Dosiseinstellposition gegen eine Bewegung gegenüber dem Gehäuse (22) längs der Ausspritzachse verriegelt ist, und eine Freigabevorrichtung (32), die an der Antriebsanordnung (34) und/oder an dem Gehäuse (22) angebracht ist und manuell betätigbar ist, um die Antriebsanordnung (34) von dem Gehäuse (22) zu entriegeln, um es zu ermöglichen, die Antriebsanordnung (34) axial gegenüber dem Gehäuse (22) zu verschieben, um die Antriebsanordnung (34) aus der Dosiseinstellposition in die Injizierposition zu bewegen, wobei die Antriebsanordnung (34) eine im allgemeinen zylindrische Muffe (34) ist, die teleskopisch innerhalb des Gehäuses (22) angeordnet ist und einen darin ausgebildeten flexiblen Finger (110,112) hat, der in eine innere Nut (158) in dem Gehäuse (22) eingreift, wenn sich die Antriebsanordnung (34) in der Dosiseinstellposition befindet, um eine Eingriffspassung damit zu bilden, um dadurch eine axiale Bewegung der Antriebsanordnung (34) gegenüber dem Gehäuse (22) zu verhindern, **dadurch gekennzeichnet, dass** die Freigabevorrichtung (32) ein im Wesentlichen zylindrischer Knopf (32) ist, der teleskopisch innerhalb der Muffe (34) angeordnet ist und einen Abschnitt vergrößerten Durchmessers (52) aufweist, der beim Vorschieben den flexiblen Finger (110, 112) der Muffe (34) löst, um es dem Finger (110,112) zu ermöglichen, sich aus dem Eingriff mit der Nut (158) in dem Gehäuse zu bewegen, um es zu ermöglichen, die Antriebsanordnung axial gegenüber dem Gehäuse (22) vorzuschieben.

Revendications

1. Appareil (20) pour la distribution d'un produit injectable, comprenant :

un corps (22) ;
un réservoir (40) monté à l'intérieur dudit corps (22) et comprenant un piston (210), une sortie et un produit injectable entre ledit piston (210) et ladite sortie, dans lequel un déplacement dudit piston (210) vers la sortie définit un axe d'éjection du produit injectable à partir du réservoir (40) ; et
une tige d'entraînement (38) placée dans ledit corps (22) et accouplée de manière à entraîner ledit piston (210) ;
un ensemble d'entraînement (34) monté dans ledit corps (22) et pouvant être axialement avancé manuellement dans ledit corps (22) entre une position de dosage et une position d'injection pour déplacer manuellement ladite tige d'entraînement (38) afin d'entraîner ledit piston (210) à l'intérieur dudit réservoir (40), ledit ensemble d'entraînement (34) étant immobilisé par rapport audit corps (22) le long de l'axe d'éjection lorsque dans ladite position de dosage, et
un dispositif de déblocage (32) fixé à au moins un dudit ensemble d'entraînement (34) et dudit corps (22) et manoeuvrable manuellement pour débloquer ledit ensemble d'entraînement (34) dudit corps (22) afin de permettre audit ensemble d'entraînement (34) d'être avancé axialement par rapport audit corps (22) pour déplacer ledit ensemble d'entraînement (34) de ladite position de dosage à ladite position d'injection, ledit ensemble d'entraînement (34) étant un cadran généralement cylindrique (34) qui est placé de manière télescopique à l'intérieur dudit corps (22), ledit cadran (34) ayant un doigt flexible (110, 112) formé à l'intérieur qui est engagé dans une rainure interne (158) dans ledit corps (22) tandis que ledit ensemble d'entraînement (34) est dans ladite position de dosage pour former un ajustement serré entre eux, empêchant ainsi un déplacement axial dudit ensemble d'entraînement (34) par rapport audit corps (22); **caractérisé en ce que** ledit dispositif de déblocage (32) est un bouton généralement cylindrique (32) qui est placé de manière télescopique dans ledit cadran (34), ledit bouton (32) comprenant une partie à diamètre agrandi (52) qui, lorsque avancée, libère ledit doigt flexible (110, 112) dudit cadran (34) pour permettre audit doigt (110, 112) de se dégager de ladite rainure (158) dans ledit corps (22) afin de permettre audit ensemble d'entraînement d'être axialement avancé par rapport au corps (22).

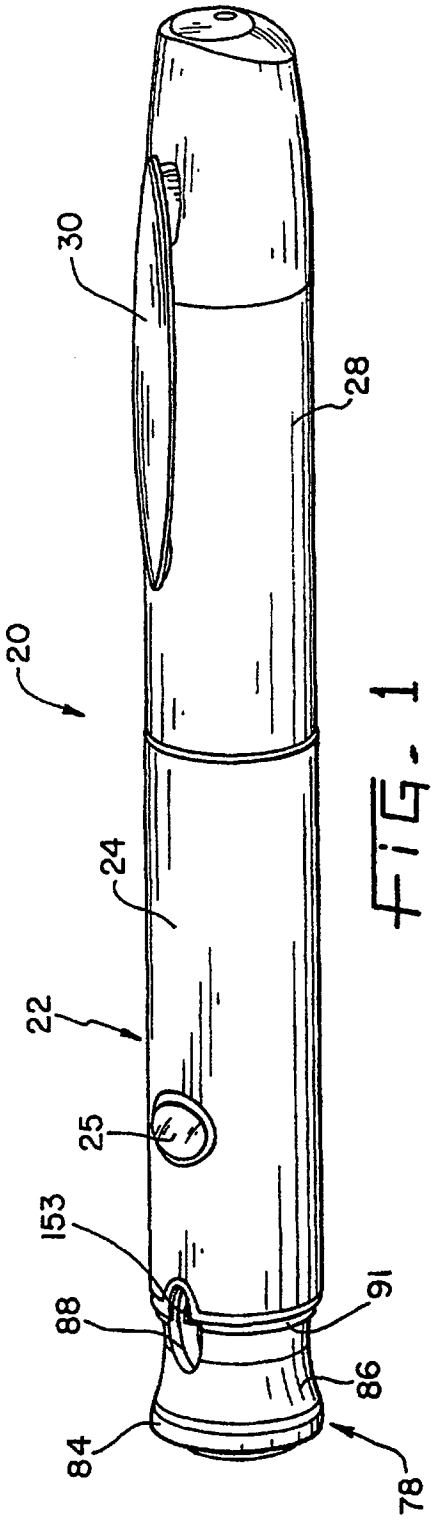
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FIG. 1

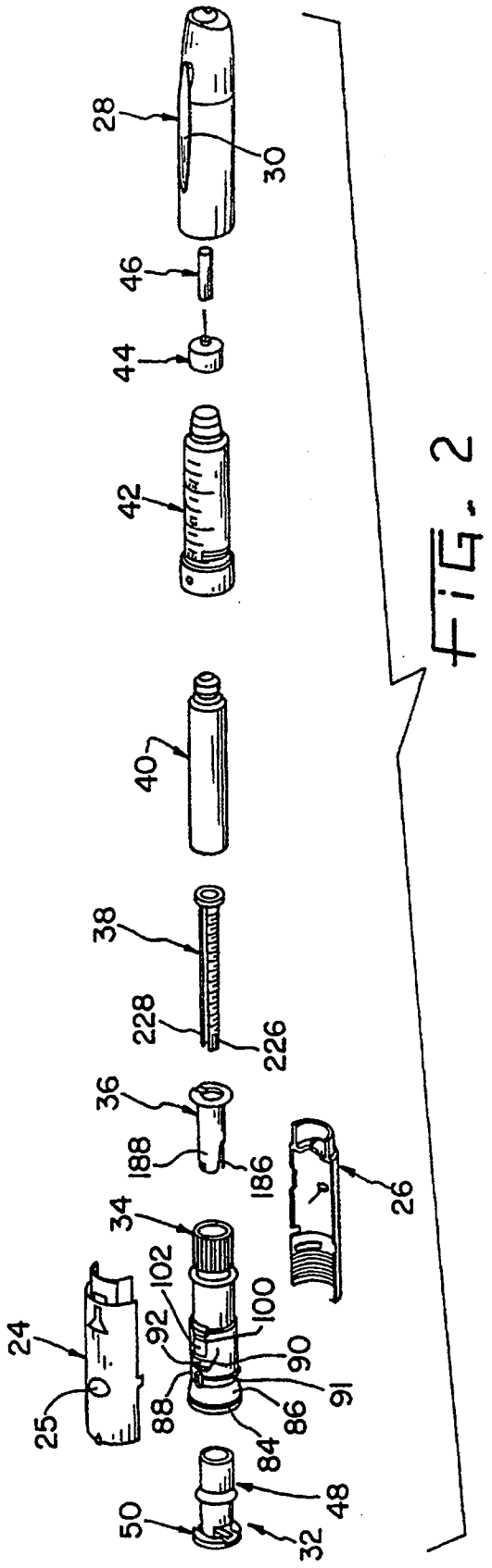
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FIG. 2

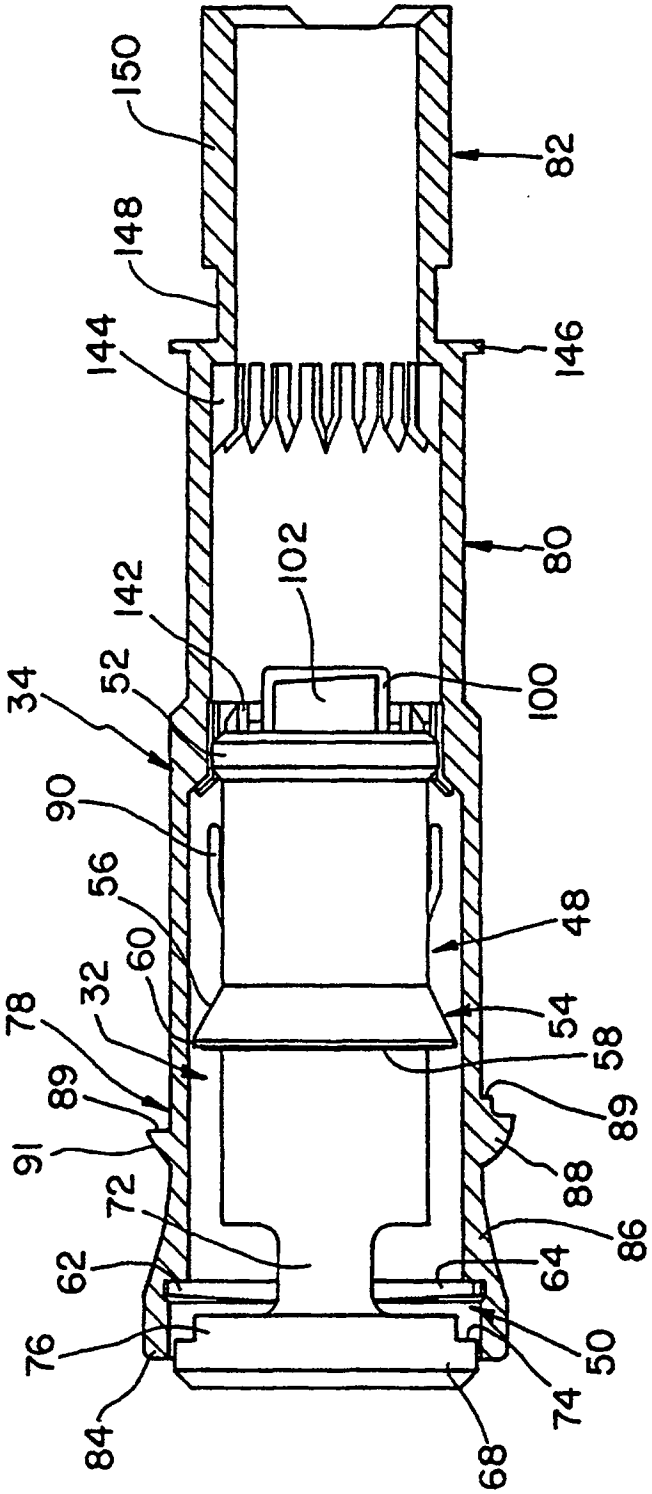
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FIG. 3

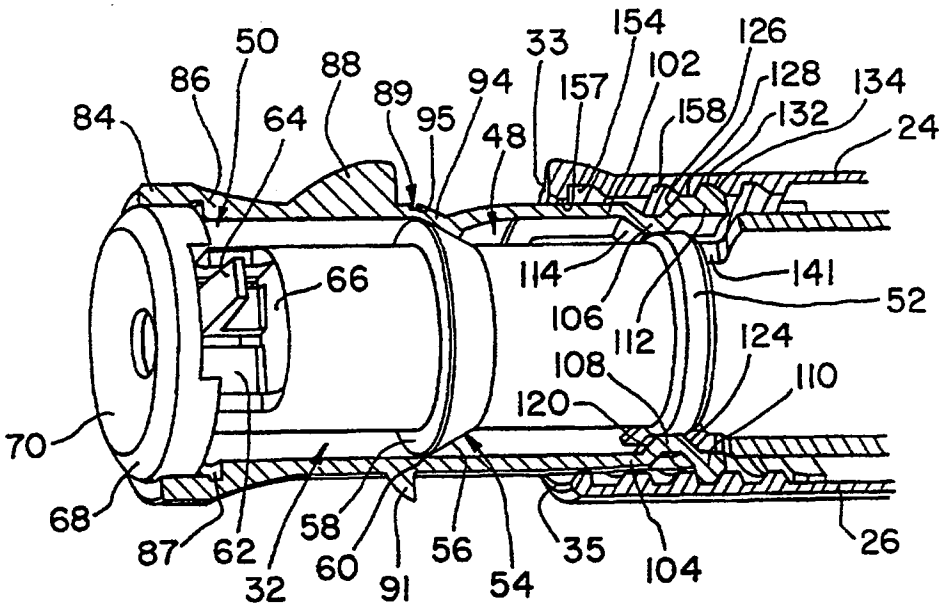
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FIG. 4

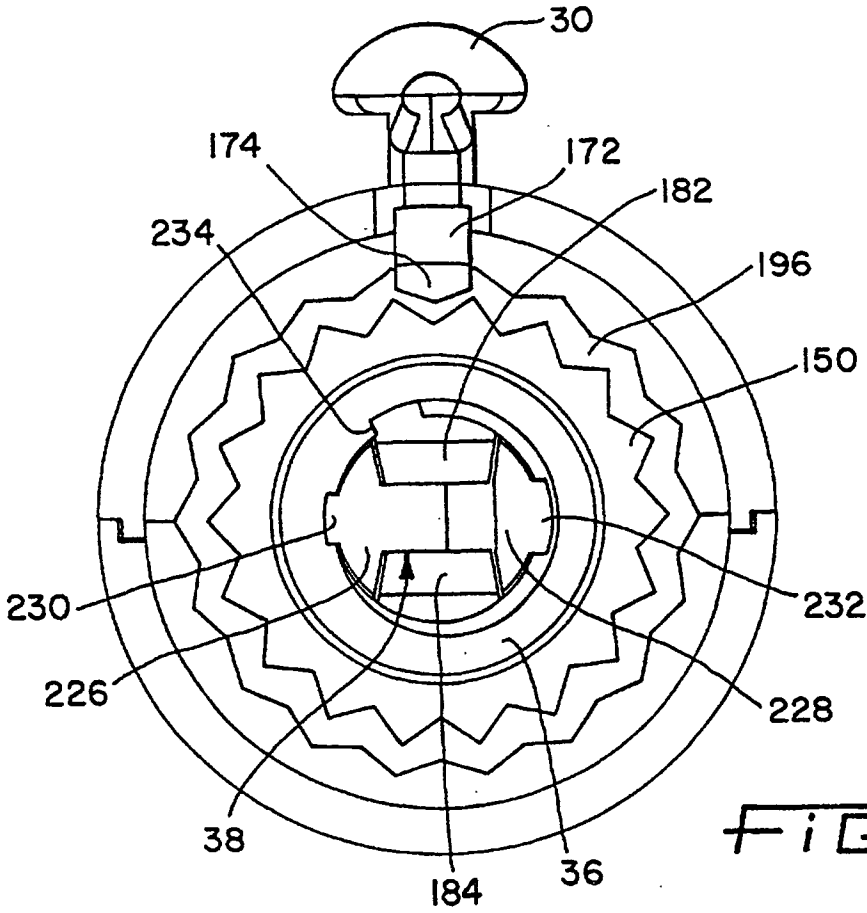
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FIG. 5

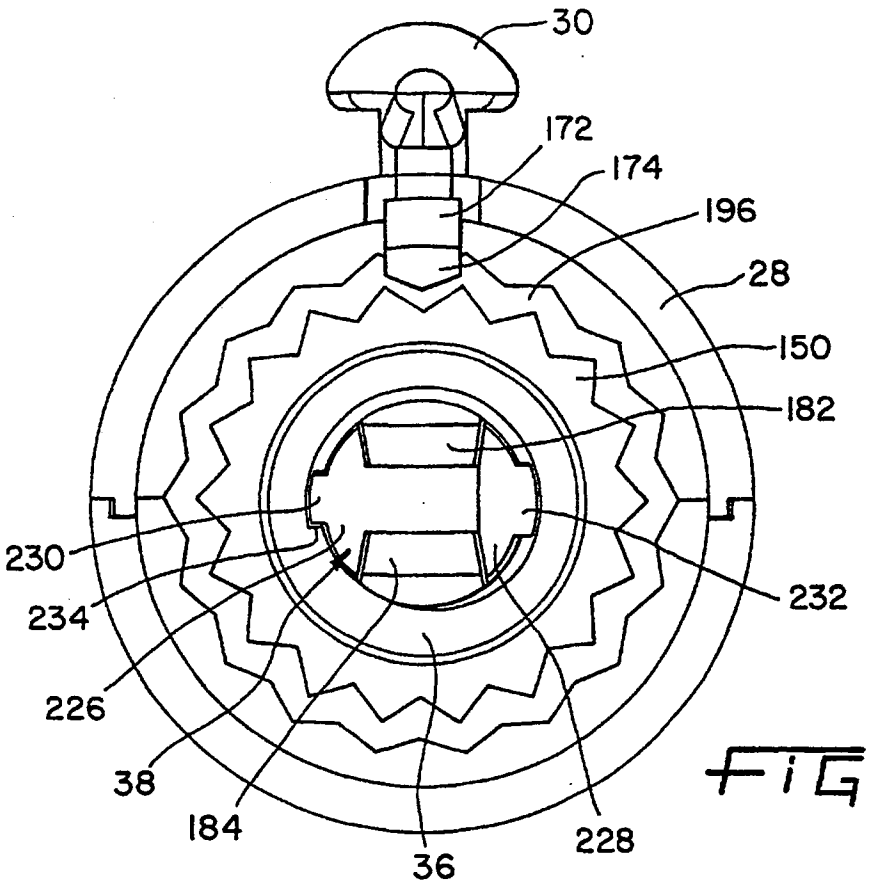
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FIG. 6

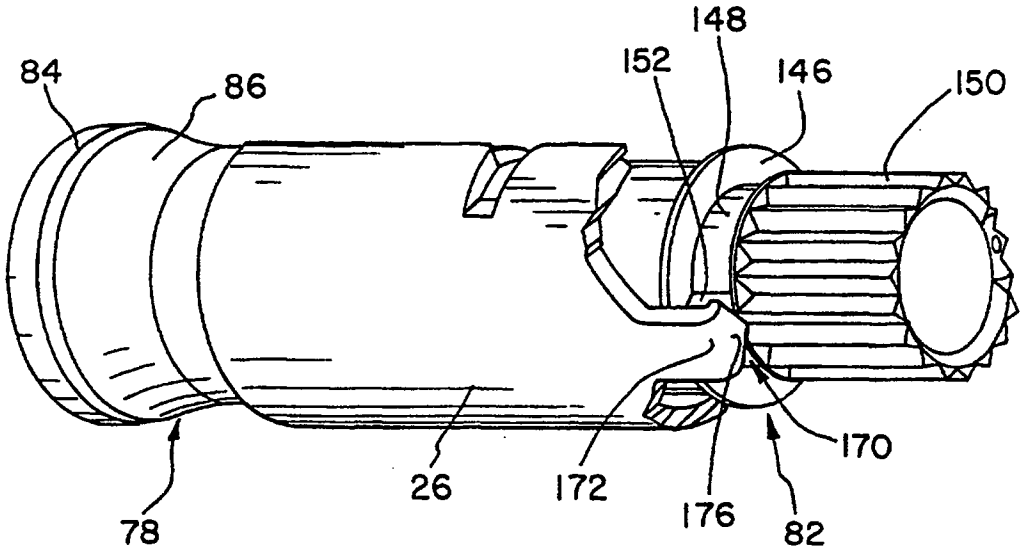
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FIG. 7

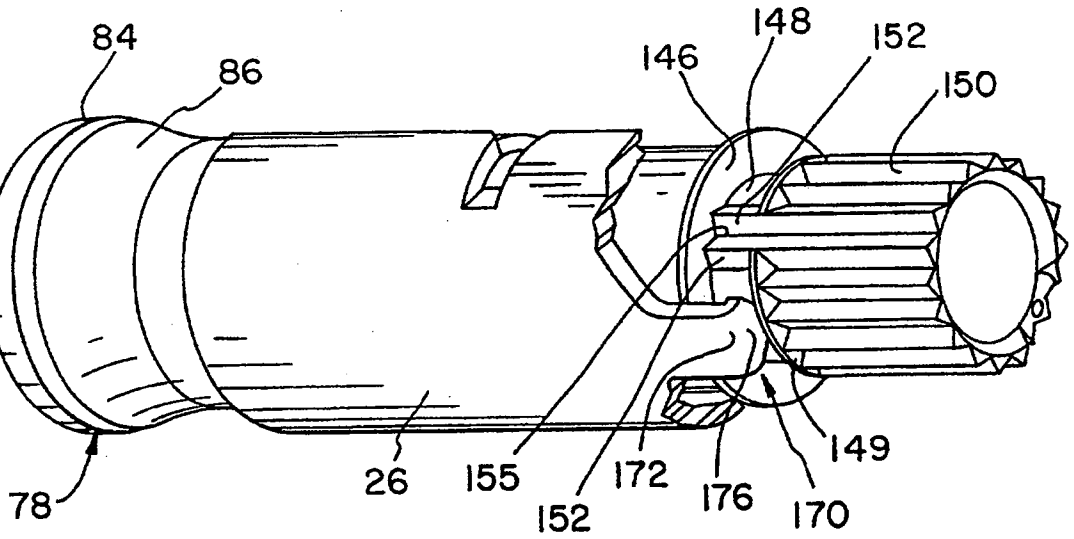
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FIG. 8

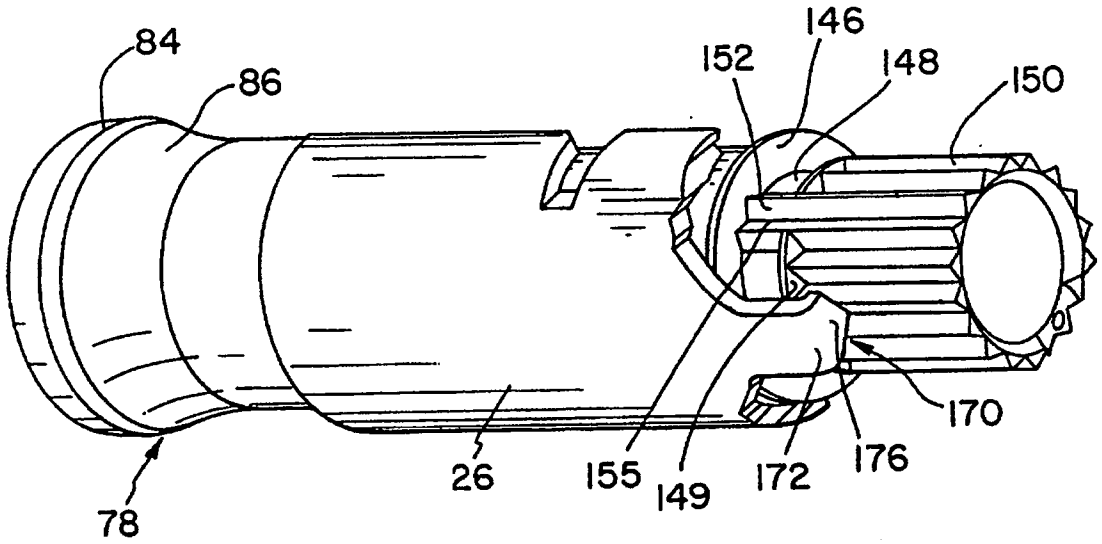
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FIG. 9

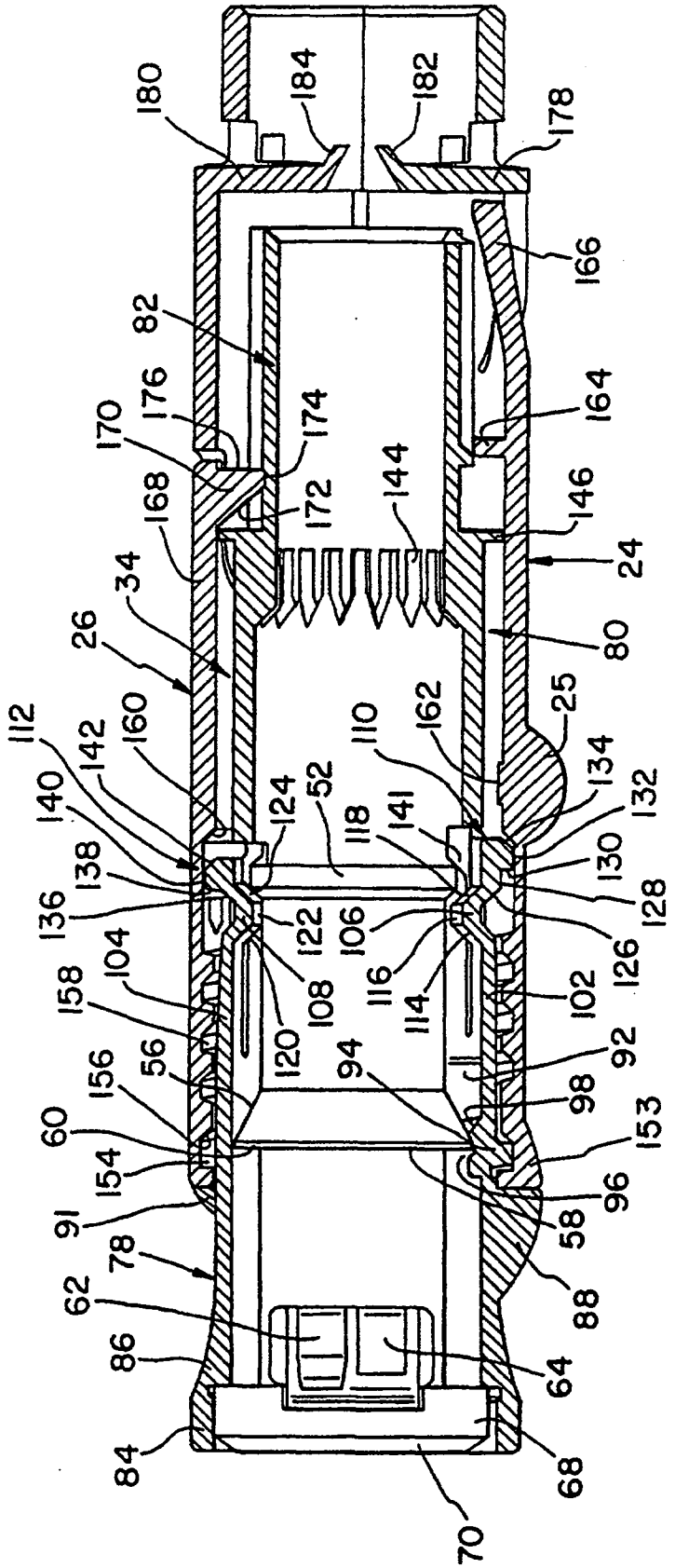
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FIG. 10

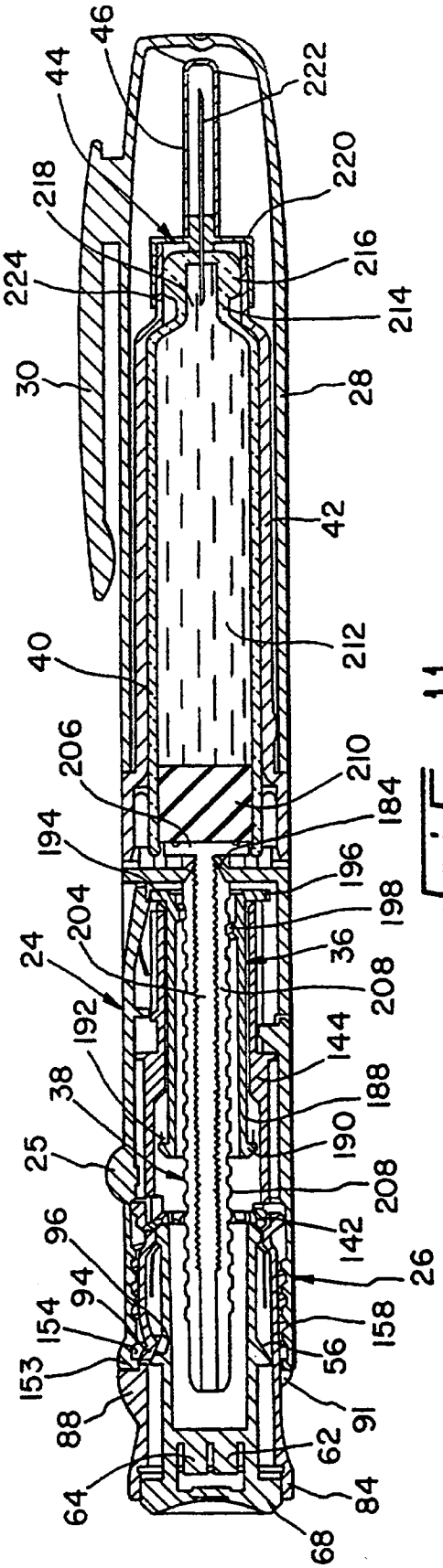
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FIG. 11

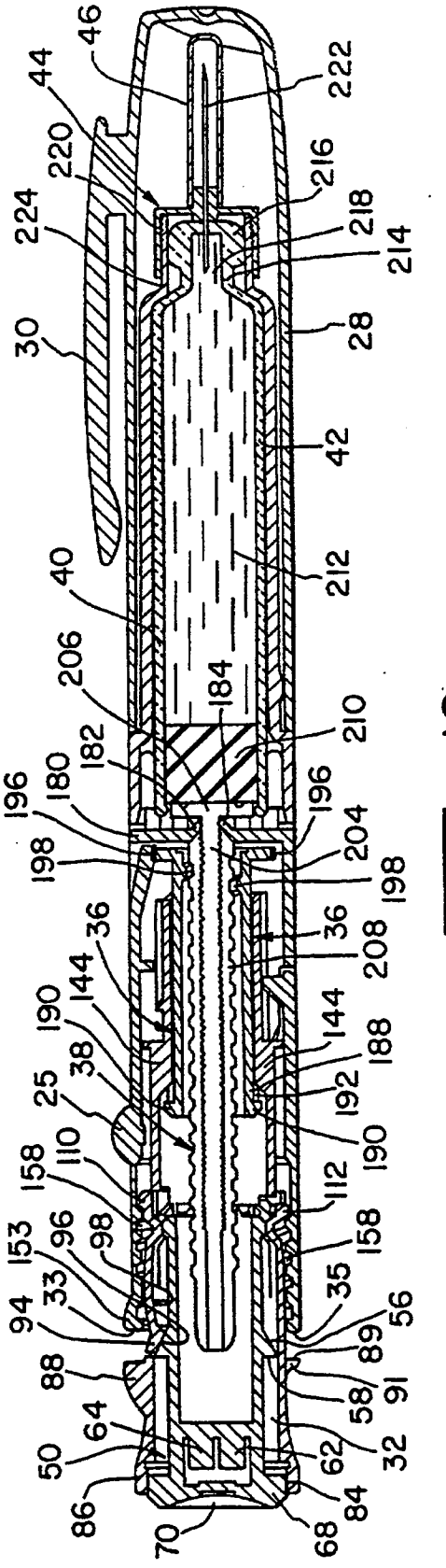
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FIG. 12

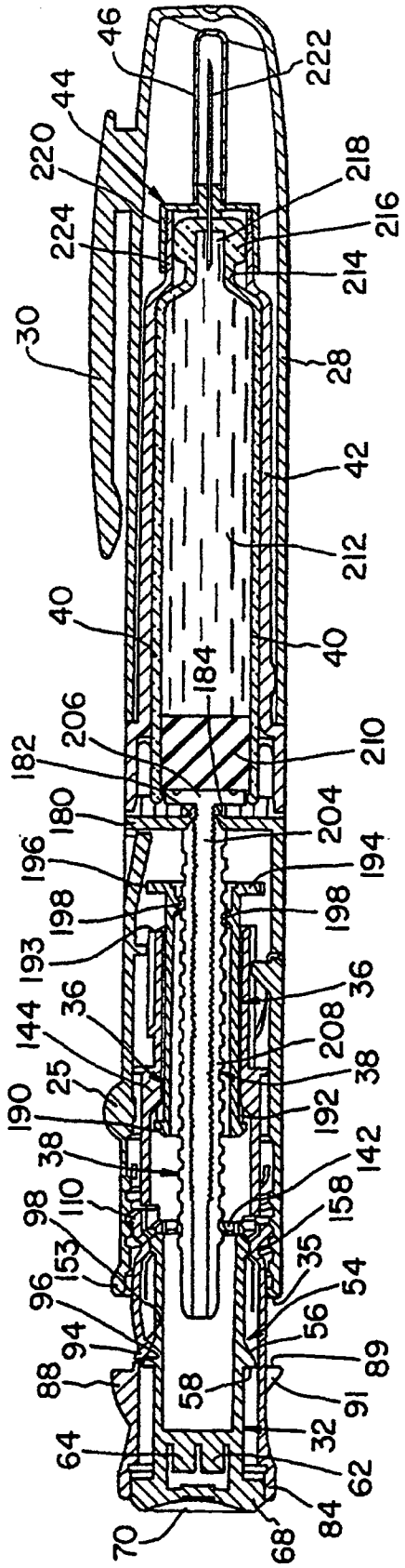
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FIG. 13

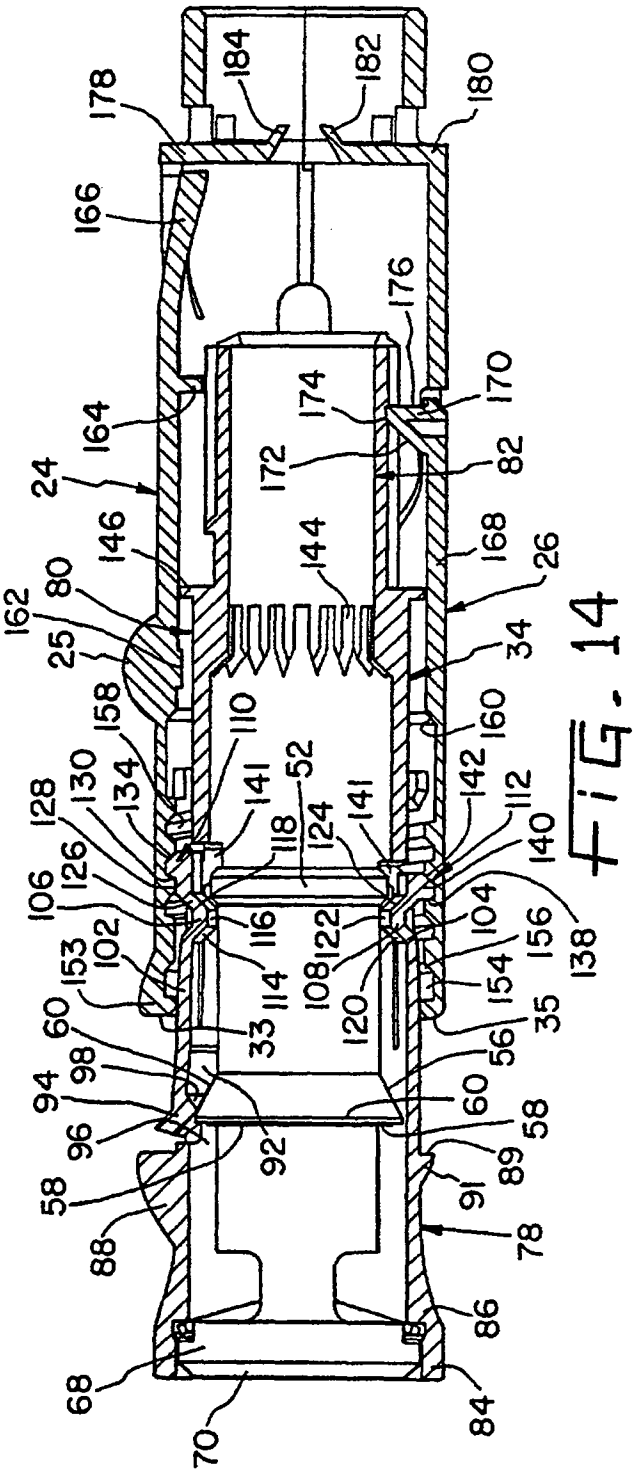
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FIG. 14

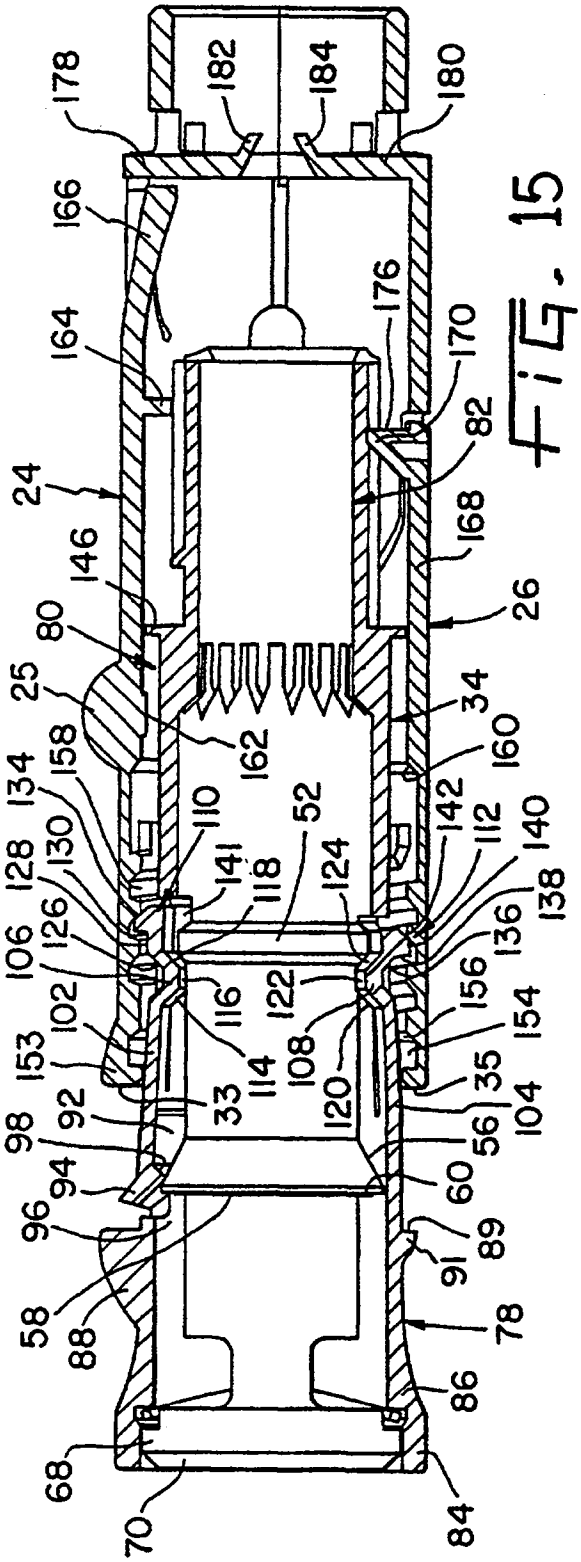
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FIG. 15

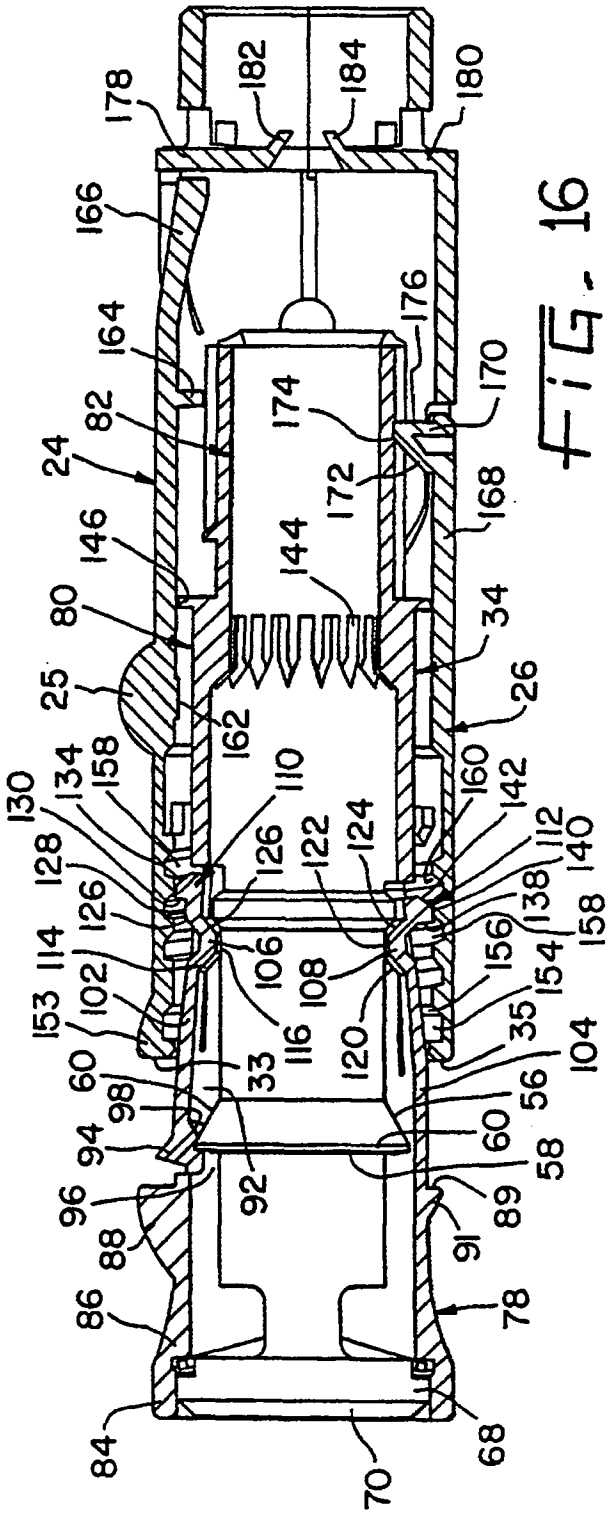
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FIG. 16

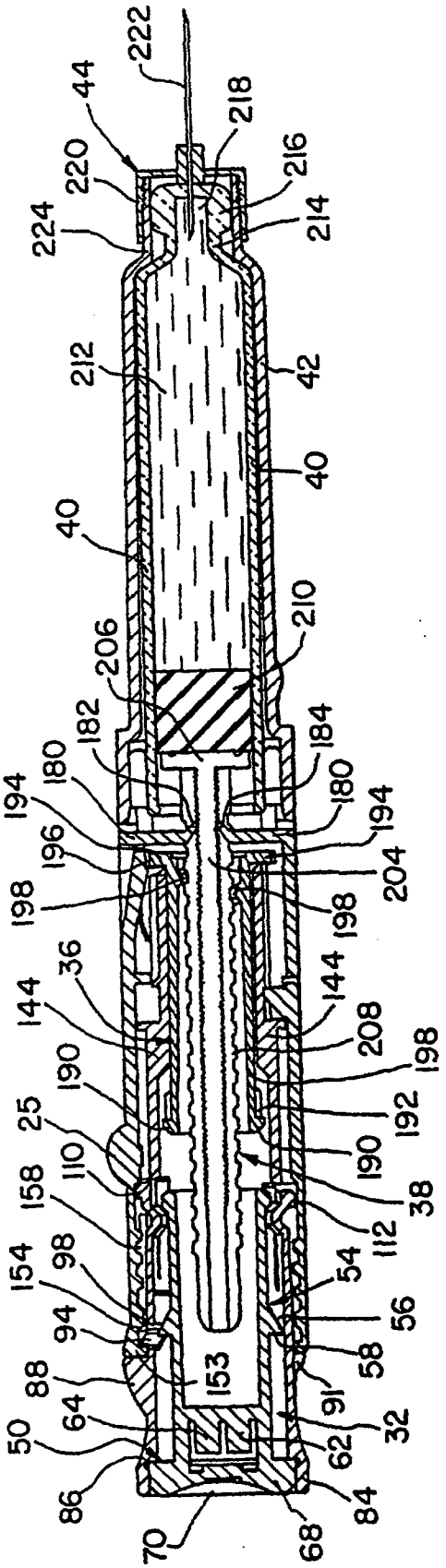
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FIG. 17

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 879 610 A3

(12) EUROPEAN PATENT APPLICATION

(88) Date of publication A3:
06.05.1999 Bulletin 1999/18

(43) Date of publication A2:
25.11.1998 Bulletin 1998/48

(21) Application number: **98202729.4**

(22) Date of filing: **06.03.1996**

(51) Int Cl.[6]: **A61M 5/315**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU NL PT SE
Designated Extension States:
AL LT LV SI

(30) Priority: **07.03.1995 US 399764**

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
96301540.9 / 0 730 876

(71) Applicant: **ELI LILLY AND COMPANY**
Indianapolis, Indiana 46285 (US)

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- **Burroughs, Andrew**
  Kenosha, Wisconsin 53143 (US)
- **Hixson, David**
  Evanston, Illinois 60202 (US)
- **Hodge, Andrew**
  Evanston, Illinois 60202 (US)

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Erl Wood Manor
Windlesham Surrey GU20 6PH (GB)

(54) Recyclable medication dispensing divice

(57) A multi-use pen-shaped medication dispensing device (20) made of a plastic material that is recyclable after the contents of the medication cartridge (40) have been exhausted. The device (20) is made of a minimal number of parts, which include a housing (22), a dial assembly (34), a generally cylindrical button assembly (32) located within the proximal end (50) of the dial assembly (34), an internally threaded nut (36), and an externally threaded leadscrew (38). The device (20) is arranged so that the dial (34) must be rotated to the zero dose position prior to setting a dose. The device (20) includes a lockout mechanism (52) that prevents the dial (34) from being depressed during dosing. The device (20) further includes a mechanism (157) that limits the maximum dosage that can be dialed up and a mechanism (230, 234) that prevents the user from dialing up a dosage greater than that remaining in the cartridge (40).

EP 0 879 610 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 20 2729

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP 0 268 191 A (HASELMEIER WILHELM FA) 25 May 1988 * the whole document * ---	1,2	A61M5/315
X	WO 92 18179 A (MEDICO DEV INVESTMENT CO) 29 October 1992 * the whole document * ---	1,4	
X	EP 0 295 075 A (HYPOGUARD UK LTD) 14 December 1988 * column 15, line 2 - line 53; figures * ---	1,4,5	
X	WO 88 08723 A (HASELMEIER WILHELM FA) 17 November 1988 * the whole document * ---	1,2	
X	EP 0 525 525 A (MEDICO DEV INVESTMENT CO) 3 February 1993 * the whole document * ---	1	
A	EP 0 554 995 A (BECTON DICKINSON CO) 11 August 1993 * the whole document * ---	1-5	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61M
A	WO 93 10838 A (NOVONORDISK AS) 10 June 1993 * the whole document * -----	1-5	

~~The present search report has been drawn up for all claims~~

Place of search	Date of completion of the search	Examiner
THE HAGUE	16 November 1998	CLARKSON P.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

European Patent Office

Application Number
EP 98 20 2729

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-5

European Patent Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 98 20 2729

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-5

   A dosing syringe having a drive assembly locked from movement in a dose setting position and a disengaging device.

2. Claim : 6

   A dosing syringe having threaded nut and drive stem with means for indicating insufficient dosage remaining.

3. Claims: 7, 8

   A method of delivering a selected dose including the steps rotating a knob to a zero position, retracting the knob to cause a dial to engage a nut, rotating the knob to rotate the nut to set a dosage and depressing the knob to inject the dose and to disengage the dial and nut.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 98 20 2729

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-11-1998

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